DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 19, 2015

Biotronik, Inc.
Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, Oregon 97035

Re: K143503
Trade/Device Name: Biomonitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MXD
Dated: January 9, 2015
Received: January 12, 2015

Dear Jon Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143503

Device Name: BioMonitor
Indications for Use:

The BioMonitor is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia
- The device has not been tested for and it is not intended for pediatric use

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

BioMonitor Implantable Cardiac Monitor with AF Detection

Traditional 510(k) Premarket Notification

1 510(K) SUMMARY

Date 510(k) Summary Prepared: March 9, 2015

Name and Address of Sponsor:
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Name and Address of Manufacturer:
BIOTRONIK SE & Co. KG (reg. no. 9610139)
Woermannkehre 1,
12359 Berlin, Germany
011-49-30-689-05-1210

Sterigenics Germany GmbH
Kasteler Straße 45
D- 65203 Wiesbaden, Germany

Contact Person(s) and Phone Number:
Jon Brumbaugh
VP, Regulatory Affairs and Compliance
Phone (888) 345-0374
Fax (800) 913-6993
jon.brumbaugh@biotronik.com

Device Name:

Trade Name:	BioMonitor
Common Name:	Implantable Cardiac Monitor
Classification Name:	Arrhythmia detector and alarm (including ST-segment measurement and alarm).
Classification:	Class II (21 CFR 870.1025)
Product Code:	MXD

General Description / Intended Use:

The BioMonitor is a small, leadless, implantable device that uses three electrodes on the body of the device to continuously monitor the patient's subcutaneous ECG. The BioMonitor is designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as bradyarrhythmia, asystole, or high ventricular rate. The device memory can store up to 13.3 min of ECG recordings from automatically detected arrhythmias and up to 22.5 min of ECG recordings from patient-triggered episodes. When a patient experiences symptoms, the ECG recordings can be manually triggered by placing a magnet over the BioMonitor. The BioMonitor is intended to aid in the diagnosis of cardiac arrhythmias in patients that may otherwise go undetected.

Predicate Devices:

- BIOTRONIK BioMonitor without AF Detection (K132960, cleared June 6, 2014)
- Medtronic Reveal XT Model 9529 (K071641, cleared November 21, 2007)
- St. Jude Medical Confirm DM 2100 (K081365, cleared August 15, 2008)

Indication for Use:

The BioMonitor is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia
- The device has not been tested for and it is not intended for pediatric use

Technological Characteristics and Substantial Equivalence:

The substantial equivalence claim between the subject and the predicate device is supported by the information included in this premarket notification. This includes the following information:

- Description of the subject and predicate devices
- Intended use of the subject and predicate devices
- Performance of the subject and predicate devices
- Technological characteristics of the subject and predicate devices
- Validation testing

Table 1: Comparison of BioMonitor with AF Detection and the Predicates

Technical Data	BioMonitor w/AF	BioMonitor	Reveal XT	Confirm DM 2100
FDA Clearance	**Subject of this 510(k)**	**K132960**	**K071641**	**K081365**
Dimensions (mm) Length x Width x Height	53.3 x 42.7 x 7.1	53.3 x 42.7 x 7.1	19 x 62 x 8	18.5 x 56.3 x 8
Volume	12.5 cc	12.5 cc	9 cc	6.5 cc
Weight	26 g	26 g	15 g	12 g
AT/AF	40 seconds/episode 30 seconds before trigger, 10 seconds after trigger	N/A	1 min/episode 30 s prior auto activation Last 30 s of episode	10 – 60 s prior activation 10- 60s post activation
MR Conditional	Yes	No	Yes	Yes

Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" in a separate submission. The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Atrial Fibrillation Feature Testing

AF Feature validation testing was completed by a functional software test to confirm that the BioMonitor detects atrial fibrillation. The device must detect the following episodes and store them in the Holter memory:

•All AF sequences exceeding the programmed confirmation time and the stability limit of adjacent QRS intervals appear as an entry in the Holter memory.

•Episodes which did not exceed the programmed stability limit or confirmation time do not appear in the Holter memory.

•AF detections or terminations are inhibited during the presence of noise resulting in:

•Complete inhibition of AF detection

•Shortening of AF episode due to noise in the beginning of the episode

•Prolonging of AF episode due to noise in the end of the episode.

MR Conditional Testing

BIOTRONIK conducted validation testing according to the Joint Working Group's International Technical Specification for ISO/TS 10974: 2012 (E). The following tests were performed:

•Gradient Induced Heating

•Vibration

•Static Malfunction

•Gradient Radiated Malfunction

•Vibration Malfunction

Clinical Study

In order to evaluate BioMonitor AF detection performance, clinical data was collected in a single-center, prospective, nonrandomized study. The ability of BioMonitor to detect episodes of AF was quantified in comparison with the gold standard, expert-annotated, external Holter ECG recorder. Fifty (50) participants with suspected paroxysmal or persistent atrial fibrillation who had been implanted with a BioMonitor were additionally equipped with an external Holter ECG recorder. Of these 50 participants, 27 showed at least one true AF episode during the two-day Holter period. A total of 131 AF episodes were annotated for 2132.9 hours of Holter ECG data.

False positive AF episodes (i.e. non-AF periods falsely detected as AF by BioMonitor), resulting in positive predictive values less than 100%, were predominately associated with episodes of ectopic beats.

False negative AF episodes (i.e. true AF episodes undetected by BioMonitor), resulting in sensitivity values less than 100%, were mainly attributed to R-R interval variability that did not exceed the BioMonitor-programmed limit of 12.5% for a sufficient fraction of intervals. All of these FN patients had AF documented by the BioMonitor in another episode and were thus identified as AF positive patients. Table 1 summarizes the mean episode sensitivity and a mean episode PPV.

Table 1: Mean BioMonitor AF Detection Performance Statistics

Sensitivity (%) ± SD	PPV (%) ± SD
94 ± 14.7	73.7 ± 40.3

List of Applied Standards

The BioMonitor was tested in accordance with the following standards:

- ANSI/AAMI PC69: 2007
- ASTM F2119-07 (2013)
- EN 45502-1: 1998

- EN 45502-2-1: 2003
- IEC 60601-2-33
- ISO/TS 10974: 2012
- ISO 14708-1
- ISO 14971: 2007

Conclusion:

BIOTRONIK considers the BioMonitor implantable cardiac monitor to be substantially equivalent to legally marketed predicate devices through the data and information presented. No safety or effectiveness issues were identified.